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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/686,865	10/16/2003	Walter Schubert	S159 1030.1	7435

7590 04/03/2006

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EXAMINER

MOSS, KERI A

ART UNIT	PAPER NUMBER
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1743

DATE MAILED: 04/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/686,865

Applicant(s)

SCHUBERT, WALTER

Examiner

Keri A. Moss

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) 11-20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on 16 October 2003 is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>10/16/03</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Election/Restrictions

1. Claims 11-20 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 2/20/2006.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
2. Claims 1-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Regarding claim 1 step c, it is unclear what exactly this step is. Is it any of three options: leaving L1, applying more L1, or applying L2 at T2 for Z2?

Claims 2-10 are rejected as dependent on claim 1.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the

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applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 1, 3, 5-10 are rejected under 35 U.S.C. 102(e) as being anticipated by Stillman (US Pub No 2003/0175827). Stillman discloses a method for preparing biological samples for analysis comprising placing the biological sample on a two-dimensional support (paragraph 10), applying protein-precipitating or denaturing solution (paragraphs 17-18), leaving the protein-precipitating or denaturing solution (paragraph 10) and drying the sample in air (paragraph 10). The biological samples are mixtures of proteins. The protein-precipitating or denaturing solution is an organic solvent (paragraphs 17-18) with critical pH values (paragraph 10) and optionally a salt solution (paragraph 17). The organic solvent is methanol or ethanol (paragraph 18). The temperature at which the reaction takes place appears to be approximately room temperature, 22 degrees celsius, which anticipates applicant's claimed range (paragraph 21). Following drying, the biological samples are subjected to protein determination (paragraph 19).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Stillman. Stillman does not disclose a method in which the sample is dried prior to adding the denaturing solution. However, changing the order of method steps is an obvious modification. In *re Burhans*, 154 F.2d 690, 69 USPQ 330 (CCPA 1946). Therefore, it would have been obvious to one of ordinary skill in the art to modify the method of Stillman by changing the order in which the drying step takes place.

8. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Stillman in view of Furuoya (USP 5,079,157). Stillman does not disclose freezing the sample after placing it on the support. Freeze-drying proteins is well known in the art for the purpose of storing precipitated or denatured proteins for future sample analysis (Furuoya Examples 1-9, 3rd paragraph). Therefore, it would have been obvious to one of ordinary skill in the art to add to the Stillman method a freeze-drying step for the ability to store the protein sample.

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9. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Stillman in view of McCaffery (USP 4,629,785). Stillman does not disclose dissolved salts of either picric acid, gallotannic acid, tungstic acid, molybdenum acid, trichloroacetic acid, perchloric acid, or suphosalicylic acid. However, Stillman discloses using a salt solution and the claimed acids are obvious functional equivalents of those that Stillman disclosed. Perchloric, trichloroacetic and tungstic acid, for example, are well known in the art to precipitate proteins, forming salt solutions (McCaffery Column 2 lines 60-65). Therefore, it would have been obvious to one of ordinary skill in the art to modify the Stillman method's salt solution with functional equivalents such as picric acid, gallotannic acid, tungstic acid, molybdenum acid, trichloroacetic acid, perchloric acid, or suphosalicylic acid.

Conclusion

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Schubert (USP 6,150,173) and Danssaert (USP 5,525,300) disclose methods of sample preparation.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Keri A. Moss whose telephone number is 571-272-8267. The examiner can normally be reached on 9-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (571) 272-1700. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

3/22/06 KAM



LYLE A. ALEXANDER
PRIMARY EXAMINER